FORM PTO-1390 (REV. 1-98) U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371

ATTORNEY'S DOCKET NUMBER	U.S. APPLICATION NO. (If known, see 37 CFR 1.5)
20-4518P	09/242700 NEW

INTERNATIONAL APPLICATION NO.	INTERNATIONAL FILING DATE	PRIORITY DATE CLAIMED
PCT/JP98/02781	June 23, 1998	June 25, 1997

TITLE OF INVENTION

A STABLE OINTMENT CONTAINING ASPIRIN

APPLICANT(S) FOR DO/EO/US

MIZOBUCHI, Noriko; HASEGAWA, Yuichi; KAWADA, Mitsuhiro; HISAICHI, Shin-ichi

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☒ This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. ☒ This express request to begin national examination procedures (35 U.S.C. 371(f)) at any time rather than delay examination until the expiration of the applicable time limit set in 35 U.S.C. 371(b) and PCT Articles 22 and 39 (1).
4. ☒ A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date
5. ☒ A copy of the International Application as filed (35 U.S.C. 371(c)(2))
   a. ☐ is transmitted herewith (required only if not transmitted by the International Bureau).
   b. ☐ has been transmitted by the International Bureau.
   c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☒ A translation of the International Application into English (35 U.S.C. 371(c)(3)).
7. ☒ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(2)).
   a. ☐ are transmitted herewith (required only if not transmitted by the International Bureau).
   b. ☐ have been transmitted by the International Bureau.
   c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
   d. ☒ have not been made and will not be made.
8. ☐ A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9. ☐ An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).
10. ☐ A translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

Items 11. to 16. below concern document(s) or information included:

11. ☒ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.

12. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.

13. ☒ A FIRST preliminary amendment.
    ☐ A SECOND or SUBSEQUENT preliminary amendment.

14. ☐ A substitute specification.

15. ☐ A change of power of attorney and/or address letter.

16. ☒ Other items or information:
    1). PCT/ISA/210 International Search Report

U.S. APPLICATION NO (if known, see 37 CFR 1.5)	INTERNATIONAL APPLICATION NO	ATTORNEY'S DOCKET NUMBER
NEW	PCT/JP98/02781	20-4518P

17. ☒ The following fees are submitted:

	CALCULATIONS	PTO USE ONLY
BASIC NATIONAL FEE (37 CFR 1.492(a)(1)-(5):		
Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO and International Search Report not prepared by the EPO or JPO. **$970.00**		
International preliminary examination fee (37 CFR 1.482) not paid to USPTO but International Search Report prepared by the EPO or JPO **$930.00**		
International preliminary examination fee (37 CFR 1.482) not paid to USPTO but international search fee (37 CFR 1.445(a)(2)) paid to USPTO. **$760.00**		
International preliminary examination fee (37 CFR 1.482) paid to USPTO but all claims did not satisfy provisions of PCT Article 33(1)-(4) **$670.00**		
International preliminary examination fee (37 CFR 1.482) paid to USPTO and all claims satisfied provisions of PCT Article 33(1)-(4). **$96.00**		
ENTER APPROPRIATE BASIC FEE AMOUNT =	$ **930.00**	
Surcharge of **$130.00** for furnishing the oath or declaration later than ☐ 20 ☒ 30 months from the earliest claimed priority date (37 CFR 1.492(e)).	$ **130.00**	

CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE		
Total Claims	3 - 20 =	0	X **$18.00**	$ **0.00**	
Independent Claims	2 - 3 =	0	X **$78.00**	$ **0.00**	
MULTIPLE DEPENDENT CLAIM(S) (if applicable)		NO	+ **$260.00**	$ **0.00**	
TOTAL OF ABOVE CALCULATIONS =				$ **1,060.00**	
Reduction of ½ for filing by small entity, if applicable. Verified Small Entity statement must also be filed (Note 37 CFR 1.9, 1.27, 1.28).				$ **0.00**	
SUBTOTAL =				$ **1,060.00**	
Processing fee of **$130.00** for furnishing the English translation later than ☐20 ☐30 months from the earliest claimed priority date (37 CFR 1.492(f)). +				$ **0.00**	
TOTAL NATIONAL FEE =				$ **1,060.00**	
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). **$40.00** per property +				$ **0.00**	
TOTAL FEES ENCLOSED =				$ **1,060.00**	
				Amount to be: refunded	$
				charged	$

a. ☒ A check in the amount of $ **1,060.00** to cover the above fees is enclosed.

b. ☐ Please charge my Deposit Account. No. _____ in the amount of $_____ to cover the above fees. A duplicate copy of this sheet is enclosed.

c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 02-2448.

NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.

Send all correspondence to:
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SIGNATURE

FARACI, C. JOSEPH
NAME

32,350
REGISTRATION NUMBER

/aam February 24, 1999

20-4518P

IN THE U.S. PATENT AND TRADEMARK OFFICE

APPLICANT: Noriko MIZOBUCHI et al.

INT'L. APPLN. NO.: PCT/JP98/02781

SERIAL NO.: NEW GROUP:

FILED: February 24, 1999 EXAMINER:

FOR: A STABLE OINTMENT CONTAINING ASPIRIN

PRELIMINARY AMENDMENT

Assistant Commissioner of Patents and Trademarks
BOX PATENT APPLICATION
Washington, D.C. 20231

February 24, 1999

Sir:

The following Preliminary Amendments and Remarks are respectfully submitted in connection with the above-identified application.

IN THE SPECIFICATION:

Before line 1, insert --This application is the national phase under 35 U.S.C. §371 of prior PCT International Application No. PCT/JP98/02781 which has an International filing date of June 23, 1998 which designated the United States of America.--

R E M A R K S

The specification has been amended to provide a cross-reference to the previously filed International Application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. §1.16 or under 37 C.F.R. §1.17; particularly, extension of time fees.

Respectfully submitted,

BIRCH, STEWART, KOLASCH & BIRCH, LLP

By _____

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CJF/aam
(Rev. 11/16/98)

DESCRIPTION

A stable ointment containing Aspirin

Technical Field

The present invention relates to a stable ointment containing Aspirin(acetyl salicylic acid).

More specifically, the present invention relates to a substantially anhydrous ointment containing Aspirin characterized in using hydrocarbon gel and/or vaseline (petrolatum) as a base, which can preserve Aspirin stably for a long term.

Background Art

Aspirin has been used as an anti-inflammatoric antipyretic analgesics from of old. It is in general orally administered in form of tablets, granules and so on.

However, due to the intestinal injury by Aspirin, its external application has been recently studied and it has been done to try to make it percutaneously absorb. The results are reported in Japanese Patent Pub. No. 3-72426 in form of ointments for treatment of neuralgia, in Japanese Patent Pub. No. 6-72879 in form of patches containing Aspirin, in Japanese Patent Pub. No. 6-183980 as a stabilizing method of Aspirin in patches containing it.

Further, patches containing Aspirin are disclosed in Japanese Patent Pub. No. 8-113531. Techniques such as improvement of transdermal absorption of Aspirin and stabilization of it in plasters are mainly disclosed in these publications. However, any technique to maintain Aspirin stably in ointments for a long term is not disclosed.

The literatures which describe methods for stabilization of Aspirin in preparations except for external preparations, are Japanese Patent Pub. No. 56-32425, Japanese Patent Pub. No. 62-89619, Japanese Patent Pub. No. 4-346930 and so on.

Because Aspirin is readily hydrolyzed even in the presence of small amount of water and furthermore, by depending on a kind of additives the hydrolysis is accelerated, in these literatures in order to avoid to contact with the additive, it is disclosed to use the protective layer consisting of sucrose, or to use binders in which water was excluded as much as possible degree and to add a hydrogenated oil as a lubricant. However, it is hardly possible to apply such techniques to ointments.

As such, in external preparations of Aspirin, the technique to secure the stability of Aspirin in preparing ointments has not been shown.

Disclosure Of Invention

The present invention was made in considering of the above problems and the object of the present invention is to provide ointments containing Aspirin which are superior in stability and can be stored for a long term.

That is, by preparing substantially water free-ointments prepared by adding Aspirin to a base comprising hydrocarbon gel and/or vaseline (petrolatum) it was found to solve the above problems and thus the present invention was completed.

Hydrocarbon gel and vaseline in the present invention are used in substantially anhydrous state. Vaseline is one ordinary used as a base for preparation of ointments, such as yellow vaseline, white vaseline and their mixture.

The amount of Aspirin in an ointment of the present invention is 0.001 to 30% by weight, preferably 0.01 to 20% by weight, more preferably 0.05 to 15% by weight. In case of more than 30% by weight of Aspirin, it is impossible to maintain the property of ointments and in addition the protection effect by the base decreases to cause hydrolysis of Aspirin. On the other hand, in case of less than 0.001% by weight of Aspirin it is hardly to exhibit the pharmacological activities of Aspirin. Either case is not preferable.

The ointments of the present invention containing Aspirin are prepared by the same method as ordinal

ointments. That is, after melting a base by warming, thereto fine powders of Aspirin are added under stirring and mixed to prepare ointments.

In case of preparation of these ointments, to add water in order to dissolve Aspirin and the like is not preferable and should be avoided.

Furthermore, it is not preferable to add any additive which destroys stability of Aspirin, such as an organic acid, an alcohol, a polyhydric alcohol, a surfactant, etc.

Best Mode for Carrying Out the Invention

The present invention is shown in more detail by the following examples. But the present invention is not limited by the examples.

Example 1

According to the following ingredients, white vaseline was put in a vacuum emulsifier (T.K.ROBO MIXER prepared by Tokusyukika Kogyo) to be melted under heating at 55 ℃. Thereto Aspirin was added and the mixture was stirred under vacuum at 2,000rpm for 15 minutes. Then the mixture was cooled to 25 °C to give ointments containing Aspirin.

Ingredients	Contents
Aspirin	0.5g
White vaseline	99.5g

Example 2

According to the following ingredients, yellow vaseline and Aspirin were put in a grinder and the mixture was stirred at 100rpm to give ointments containing Aspirin.

Ingredients	Contents
Aspirin	8.0g
Yellow vaseline	92.0g

Example 3

According to the following ingredients, hydrocarbon gel and Aspirin were put in a grinder and the mixture was stirred at 80rpm to give ointments containing Aspirin.

Ingredients	Contents
Aspirin	5.0g
Hydrocarbon gel	99.5g
(Japanese Pharmaceutical Excipients)	

Example 4

According to the following ingredients, hydrocarbon

gel and Aspirin were put in a planetary mixer and the mixture was stirred under vacuum at 130rpm for 20 minutes to give ointments containing Aspirin.

Ingredients	Contents
Aspirin	25.0g
Hydrocarbon gel	75.0g
(Japanese Pharmaceutical Excipients)	

Example 5

According to the following ingredients and the method described in Example 4, there were obtained ointments containing Aspirin.

Ingredients	Contents
Aspirin	0.5g
Hydrocarbon gel	99.5g
(Japanese Pharmaceutical Excipients)	

Example 6

According to the following ingredients and the method described in Example 4, there were obtained ointments containing Aspirin.

Ingredients	Contents
Aspirin	1.0g
Hydrocarbon gel	79.0g
(Japanese Pharmaceutical Excipients)	
White vaseline	20.0g

Comparative Example 1

According to the following ingredients, polyacrylic acid was added to propylene glycol and the mixture was melted by warming on a water bath and stirred. Then, Aspirin was dissolved in the mixture and thereto triethanolamine was added. The mixture was stirred to give gelation ointments.

Ingredients	Contents
Aspirin	0.5g
Polyacrylic acid	0.5g
Propylene glycol	45.0g
Triethanolamine	0.67g
Purified water	residual
Total	100.0g

Comparative Example 2

According to the following ingredients, carboxymethyl cellulose sodium was dispersed in ethanol. The mixture was

added to a mixture of glycerin and propylene glycol under stirring. Then, Aspirin was dispersed and dissolved in the mixture. Thereto purified water was added and the mixture was stirred thoroughly to give gelation ointments.

Ingredients	Contents
Aspirin	0.5g
Carboxymethyl cellulose sodium	6.0g
Ethanol	8.0g
Glycerin	20.0g
Propylene glycol	20.0g
Purified water	residual
Total	100.0g

Comparative Example 3

According to the following ingredients, hydrophilic ointments described in the Pharmacopeia of Japan XIII was prepared and thereto Aspirin was mixed to prepare a ointment.

Ingredient of hydrophilic ointment	
White vaseline	25.0g
Stearyl alcohol	20.0g
Propylene glycol	12.0g
Polyoxyethylene hyroganated castor oil	4.0g

Glycerol monostearate	1.0g
p-Hydoxybenzoic acid methyl ester	0.1g
p-Hydoxybenzoic acid propyl ester	0.1g
Purified water	residual
Total	100.0g

Ingredients of ointment containing Aspirin

Aspirin	0.5g
Hydrophilic ointment	99.5g

Experiment 1

Ointments of the present invention prepared by Examples 1 and 5, and ointments prepared by Comparative Examples 1 to 4 were tested on stability in strage at 75% RH at 40°C, and at 50°C. Test samples were stored under each condition for one or two months, and after sampling, contents of Aspirin remaining in each sample were measured and the remaining percentage per initial contents was calculated and shown in Table 1.

Experiment 2

Ointments of the present invention prepared by examples 1 to 5 and ointments prepared by Comparative Example 1 were measured on the water contents in them by Karl-Fischer moisture content meter and the results were

shown in Table 2.

Table 1. Test result on the stability of ointments containing Aspirin

	75%RH at 40°C remain (%)				at 50°C remain (%)			
	Initial	1	2	10.5	Initial	1	2	10.5
Example 1	100	100.6	1002.4	96.9	100	96.0	97.8	91.7
Example 5	100	101.2	1002.4	96.4	100	100.0	99.4	93.2
Comp. Ex.1	1001	15.4	1.2	0	100	0.8		0
Comp. Ex.2	100	13.8	1.4	0	100	0	0	
Comp. Ex.3	100	20.7	0.4	0	100	0	0	

Table 2. The result of measurement of water content in ointments containing Aspirin

	Ex.1	Ex.2	Ex.3	Ex.4	Ex.5	Com.Ex. 1	Com.Ex. 2	Com.Ex. 3
water contents (%)	0.0190	0.0261	0.0098	0.0127	0.0066	55.2438	45.2190	38.0261

Industrial Applicability

The ointments of the present invention containing Aspirin can be stored stably Aspirin for a long term in form of the substantially anhydrous ointment containing hydrocarbon gel and/or vaseline as a base.

CLAIMS

1. A substantially anhydrous ointment containing Aspirin which is characterized in using hydrocarbon gel and/or vaseline as a base.

2. A stable ointment containing Aspirin and a base consisting of at least one compound selected from hydrocarbon gel and vaseline.

3. The ointment of claim 2 wherein the content of Aspirin 0.001 to 30% weight per total amount.

ABSTRACT

A substantially anhydrous stable ointment containing Aspirin which is characterized in using gelation hydrocarbon and/or vaseline as a base. The ointment is superior in stability and can be stored for a long term.

BIRCH, STEWART, KOLASCH & BIRCH, LLP

PLEASE NOTE: YOU MUST COMPLETE THE FOLLOWING:

COMBINED DECLARATION AND POWER OF ATTORNEY

FOR PATENT AND DESIGN APPLICATIONS

ATTORNEY DOCKET NO. 20-4518P

As a below named inventor, I hereby declare that: my residence, post office address and citizenship are as stated next to my name; that I verily believe that I am the original, first and sole inventor (if only one inventor is named below) or an original, first and joint inventor (if plural inventors are named below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

Insert Title: A stable ointment containing Aspirin

Fill in Appropriate Information - For Use Without Specification Attached:

the specification of which is attached hereto. If not attached hereto,

the specification was filed on February 24, 1999 as

United States Application Number _____; and /or

the specification was filed on June 23, 1998 as PCT

International Application Number PCT/JP98/02781; and was

amended under PCT Article 19 on _____ (if applicable)

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations, §1.56.

I do not know and do not believe the same was ever known or used in the United States of America before my or our invention thereof, or patented or described in any printed publication in any country before my or our invention thereof or more than one year prior to this application, that the same was not in public use or on sale in the United States of America more than one year prior to this application, that the invention has not been patented or made the subject of an inventor's certificate issued before the date of this application in any country foreign to the United States of America on an application filed by me or my legal representatives or assigns more than twelve months (six months for designs) prior to this application, and that no application for patent or inventor's certificate on this invention has been filed in any country foreign to the United States of America prior to this application by me or my legal representatives or assigns, except as follows.

I hereby claim foreign priority benefits under Title 35, United States Code, §119 (a)-(d) of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:

Insert Priority Information: (if appropriate)

Prior Foreign Application(s)			Priority Claimed	
168513/1997 (Number)	Japan (Country)	06/25/1997 (Month/Day/Year Filed)	☒ Yes	☐ No
(Number)	(Country)	(Month/Day/Year Filed)	☐ Yes	☐ No
(Number)	(Country)	(Month/Day/Year Filed)	☐ Yes	☐ No
(Number)	(Country)	(Month/Day/Year Filed)	☐ Yes	☐ No
(Number)	(Country)	(Month/Day/Year Filed)	☐ Yes	☐ No

Insert Provisional Application(s): (if any)

I hereby claim the benefit under Title 35, United States Code, §119(e) of any United States provisional application(s) listed below.

(Application Number) (Filing Date)

(Application Number) (Filing Date)

Insert Requested Information: (if appropriate)

All Foreign Applications, if any, for any Patent or Inventor's Certificate Filed More Than 12 Months (6 Months for Designs) Prior To The Filing Date of This Application:

Country	Application No	Date of Filing (Month/Day/Year)

I hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations, §1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application:

Insert Prior U.S. Application(s): (if any)

(Application Number)	(Filing Date)	(Status - patented, pending, abandoned)
(Application Number)	(Filing Date)	(Status - patented, pending, abandoned)

I hereby appoint the following attorneys to prosecute this application and/or an international application based on this application and to transact all business in the Patent and Trademark Office connected therewith and in connection with the resulting patent based on instructions received from the entity who first sent the application papers to the attorneys identified below, unless the inventor(s) or assignee provides said attorneys with a written notice to the contrary:

Terrell C. Birch	(Reg. No. 19,382)	Raymond C. Stewart	(Reg. No. 21,066)
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PLEASE NOTE: YOU MUST COMPLETE THE FOLLOWING:

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full Name of First or Sole Inventor: Insert Name of Inventor Insert Date This Document is Signed

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* DATE OF SIGNATURE